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In The
Supreme Court of the United States

CHARLES R. RIEGEL and
DONNA S. RIEGEL,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF OF THE PUBLIC HEALTH ADVOCACY INSTITUTE, PRESCRIPTION ACCESS LITIGATION LLC, AND COMMUNITY RIGHTS COUNSEL AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

TIMOTHY J. DOWLING
COMMUNITY RIGHTS COUNSEL
1301 Connecticut Ave. NW
Suite 502
Washington, D.C. 20036
(202) 296-6889

Counsel for Amici Curiae

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

QUESTION PRESENTED

Amici address the following question:

Whether an express preemption provision preempts State law claims where the provision fails to contain an unambiguous statement reflecting Congress's intent to include the State law claims within the scope of preemption.

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INTEREST OF THE *AMICI CURIAE*[1]

The Public Health Advocacy Institute is a nonprofit organization founded in 1979 and located at Northeastern University School of Law in Boston. The Institute is devoted to supporting and enhancing public health understanding and commitment among law teachers and students, legislators, regulators, the courts, and others who shape public policy through the law. Its primary area of research and scholarship focuses on legal strategies to reduce the adverse public health impact of tobacco industry products.

Prescription Access Litigation LLC (PAL) is a nonprofit organization that uses litigation and consumer education to challenge illegal pharmaceutical industry tactics. PAL is a coalition of over 130 State, local, and national organizations, including senior citizen groups, consumer advocates, health care advocates, legal services offices, nonprofit health plans, labor unions, and union benefit funds. The members of the PAL coalition have a combined membership of over 13 million individuals. A number of PAL member organizations are plaintiffs in lawsuits regarding drug marketing and advertising that involve preemption issues under the Federal Food, Drug, and Cosmetic Act.

Community Rights Counsel (CRC) is a nonprofit public interest law firm that assists State and local officials and others in defending against constitutional challenges to

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[1] The parties have consented to the filing of this brief, and letters reflecting that consent have been filed with the Clerk. This brief was not authored in whole or in part by counsel for a party, and no person or entity other than *amici*, their members, and their counsel made a monetary contribution to the preparation or submission of this brief.

State and local protections, with a particular emphasis on challenges under the Supremacy Clause and Takings Clause. Since its founding in 1997, CRC has filed *amicus* briefs in preemption cases before this Court in support of many State and local laws. It also has represented scores of governmental and nonprofit organizations in federal and State appellate courts across the country.

Amici believe that the public cannot be adequately protected against dangerous medical devices and other products without effective State law tort remedies. *Amici* thus have a strong interest in this case and the development of preemption law generally.

SUMMARY OF ARGUMENT

There is a presumption against preemption, and that presumption is especially strong where the subject matter at issue implicates the States' historic police power to protect public health and safety. The Court refuses to find preemption of State law unless "the nature of the regulated subject matter permits no other conclusion" or "the Congress has unmistakably so ordained." *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963)).

In express preemption cases, the Court implements this strong presumption against preemption by requiring that the preemption provision be "nonambiguous." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005). The preemptive statement must be pellucidly clear not only as to the *fact* of preemption, but also as to its *scope*, providing unmistakable evidence that the challenged State laws fall

within the boundaries of preemptive act. Express preemption provisions should be narrowly interpreted, and any ambiguities must be construed against preemption, with ties going to the States.

Application of these fundamental interpretive principles in defining the scope of express preemption provisions promotes several values critical to our federal system. Appropriate respect for State sovereignty is essential to the ability of the States to serve as laboratories of experimentation on important issues of public policy. State officials are best positioned to evaluate the diverse conditions across the nation and gauge the needs of the citizenry through appropriately tailored laws and remedies. The requirement that express preemption provisions be unambiguous derives from and enhances this vital role played by the States in our federal system.

Requiring express preemption provisions to be completely clear as to their scope also allows federal officials to be held accountable when they override the voter preferences reflected in State laws, including decisions by State legislatures to retain common law remedies. When special interests persuade federal legislators to abolish widely supported State law protections, the requirement that express preemption provisions be unambiguous helps to ensure that those legislators face the appropriate consequences in subsequent elections.

The interpretive principles that apply to express preemption provisions also promote clarity and predictability in the law. Federal courts should not casually infer congressional intent to preempt longstanding State common law remedies. Just as courts decline to read one statute as repealing another absent a clear mandate, or

refrain from applying a statute retroactively without clear authorization to do so, the requirement that express preemption provisions be unambiguous as to their scope helps to protect settled expectations, enhance predictability, and preserve clarity in the law.

ARGUMENT

This is a case about federalism. Its proper resolution depends on the application of neutral principles that promote State sovereignty, the role of the States as laboratories of policy experimentation, and other essential elements of "Our Federalism." *Younger v. Harris*, 401 U.S. 37, 44 (1971).

Indeed, preemption cases often provide the best test of the judiciary's commitment to federalist principles. A distinguished federal appellate task force led by then-Judge Kenneth Starr opened its comprehensive report on preemption by emphasizing that "[f]ederal preemption of state law implicates fundamental issues of governmental authority that go to the very heart of our federal system." Kenneth Starr, *et al.*, THE LAW OF PREEMPTION: A REPORT OF THE APPELLATE JUDGES CONFERENCE, 1 (ABA 1991) (hereinafter "STARR REPORT ON PREEMPTION"); *accord Egelhoff v. Egelhoff*, 532 U.S. 141, 160-161 (2001) (Breyer, J., dissenting) ("[T]he true test of federalist principle may lie * * * in those many statutory cases where courts interpret the mass of technical detail that is the ordinary diet of the law."; citations omitted).

The Riegels' opening brief explains why the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act, specifically 21 U.S.C. § 360k(a),

does not preempt the State common law claims at issue, and *amici* need not repeat those arguments here. Instead, we address a single, but highly significant, interpretive rule that bears on the question presented, namely the requirement that Congress provide a clear, unambiguous textual description of the scope of preemption in express preemption provisions such as section 360k(a).

Even without this rule, the Riegels should prevail because, as shown in their brief, the best reading of section 360k(a) allows the State law claims to proceed. But if this Court were to conclude that section 360k(a) is ambiguous on the issue, the Riegels still should prevail because that provision does not contain a clear and unambiguous statement that these State law claims are preempted.

I. BINDING PRECEDENT REQUIRES AN EXPRESS PREEMPTION PROVISION TO BE CLEAR AND UNAMBIGUOUS AS TO ITS SCOPE AND APPLICATION.

There is a strong presumption against preemption, and its pedigree runs deep. For more than eighty years, the Court has stressed that it "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (citing cases extending back to 1926). The Court uses very demanding language to articulate this strong presumption, insisting that there is no preemption unless "the nature of the regulated subject matter permits no other conclusion" or "Congress has unmistakably so ordained." *Chicago & N.W.*

Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311, 317 (1981) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963)).[2]

In express preemption cases,[3] the Court implements this strong presumption against preemption by requiring that the preemption provision be clear as to its scope, and by resolving textual ambiguities against preemption. For example, in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), the Court addressed whether an express preemption provision in a federal pesticide statute preempts State common law and statutory tort actions. The Court made clear that any ambiguity in the express preemption provision must be read as cutting against preemption:

> Even if Dow had offered us a plausible alternative reading of § 136v(b) – indeed, even if its alternative reading were just as plausible as our reading of that text – we would nevertheless have a duty to accept the reading that disfavors preemption.

Id. at 449. After reciting the presumption against preemption, the *Bates* Court ruled that the express preemption

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[2] Unlike the instant case, the nature of the subject matter might suggest preemption when the challenged State law bears upon peculiarly federal interests, such as foreign policy or immigration. *See Hines v. Davidowitz*, 312 U.S. 52 (1941). There is no peculiarly federal interest at issue here.

[3] This brief addresses only express preemption, but it is worth noting that in cases involving implied preemption, the strong presumption against preemption applies with equal force, and Congress's intent to preempt still must be "clear and manifest." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 69 (2002) (citation omitted). The exacting rules governing the proper reading of express preemption provisions comfortably coexist with the demanding legal standards that govern implied preemption.

provision before it would not apply to State law tort claims absent "a nonambiguous command" in the text of the provision. *Id.* In other words, where there is ambiguity, there is no preemption. And where ambiguity leaves the interpretive enterprise in perfect equipoise – even where the preemptive reading is "just as plausible" as the *Bates* Court put it (*id.*) – ties go to the preservation of State law. The *Bates* Court found it "particularly dubious" that the federal pesticide law contained "a nonambiguous command" to preempt various tort claims at issue there, given that the United States had taken conflicting positions on the matter. *Id.*

In *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), the Court implemented the presumption against preemption by narrowly construing an express preemption provision in the federal law governing cigarette labeling and advertising. As the Court put it, the presumption "reinforces the appropriateness of a narrow reading" of the express preemption provision. *Id.* at 518; *accord id.* at 523 (plurality) ("[W]e must fairly but – in light of the strong presumption against pre-emption – narrowly construe the precise language of §5(b) * * * .").

More significantly, in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court relied on *Cipollone* to support a narrow construction of the very provision at issue here, section 360k(a). *Id.* at 485. The *Medtronic* Court expressly rejected the argument that this presumption, as well as the resulting narrowing construction, do not apply to the scope of an express preemption provision:

> Although dissenting Justices have argued that this assumption should apply only to the question whether Congress intended any pre-emption at all, as opposed to questions concerning the

> *scope* of its intended invalidation of state law, we used a "presumption against the pre-emption of state police power regulations" to support a narrow interpretation of such an express command in *Cipollone*.

Id. (emphasis in original; citation omitted).

These interpretive principles requiring complete clarity in express preemption provisions find support not only in *Bates*, *Cipollone*, *Medtronic*, and other preemption cases, but also in rulings imposing analogous clear statement rules designed to promote federalism. For example, out of respect for State sovereignty and State prerogatives, the Court will find congressional abrogation of State sovereign immunity only where the plain text of a federal statute makes the abrogation "unmistakably clear." *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985); *accord, Lane v. Pena*, 518 U.S. 187, 192 (1996) (waiver "must be unequivocally expressed in the statutory text"); *Library of Congress v. Shaw*, 478 U.S. 310, 318 (1986) (there can by no waiver "by use of ambiguous language"). Like the requirement to avoid ambiguity that applies to express preemption provisions, the clear statement requirement for abrogation of sovereign immunity applies not only to the existence of a waiver, but to its scope as well. *E.g.*, *Lane*, 518 U.S. at 192 (a waiver of sovereign immunity "will be strictly construed, in terms of its scope, in favor of the sovereign").

Of course, no one would argue that the interpretive principles that apply to sovereign immunity are identical in all respects to those that govern preemption cases. One obvious difference is that the Court recognizes implied preemption in limited circumstances, but does not recognize implied immunity waivers. But in express preemption

cases, the jurisprudence that governs immunity waivers provides an especially helpful analogy because it is rooted in the same fundamental principles regarding respect for State sovereignty.

In short, the Congress may not impinge upon State sovereignty or readjust the federal-State balance through an express preemption provision that is ambiguous as to whether the State authority at issue is preempted. Express preemption provisions must be completely clear that the challenged State laws fall within the scope of the provision, with ambiguities resolved against preemption. As the Riegels' brief demonstrates, section 360k(a) does not contain a clear statement that reflects Congress's unmistakable intent to preempt the State common law remedies at issue. Accordingly, there is no preemption.

II. THE REQUIREMENT THAT EXPRESS PREEMPTION PROVISIONS BE UNAMBIGUOUS RESPECTS THE PROPER ROLE OF THE STATES IN OUR FEDERAL SYSTEM.

The political and policy rationales that underlie "Our Federalism" help to explain why express preemption provisions must be clear and unambiguous regarding their application to a challenged State law.

First, our federal system reflects the fundamental truth that, absent a compelling need for national uniformity, government officials closest to the people are most responsive to their desires. *E.g.*, *Younger v. Harris*, 401 U.S. at 44 (explaining that federalism is not "blind deference to 'States Rights' " but is instead based on "the belief that the National Government will fare best if the States and their institutions are left free to perform their separate

functions in their separate ways."); Steven G. Calabresi, *"A Government of Limited and Enumerated Powers": In Defense of* United States v. Lopez, 94 Mich. L. Rev. 752, 775 (1995) (explaining that federalism improves the quality of government decision-making due to increased information flow and greater efficiency at the State level, and by ensuring policymakers are better informed of the costs and benefits of competing policy options).

Second, State laws often are more effective than a one-size-fits-all national policy because they can be tailored to fit regional and local conditions. *E.g.*, *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991) ("This federalist structure of joint sovereigns * * * assures a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society."); Michael W. McConnell, *Federalism: Evaluating the Founders' Design*, 54 U. Chi. L. Rev. 1484, 1493 (1987) ("The first, and most axiomatic, advantage of decentralized government is that local laws can be adapted to local conditions and local tastes * * * .").

Third, a diversity of State laws allows the States to act as laboratories of experimentation on important issues of public policy. The classic statement of this advantage appears in Justice Brandeis's dissent in *New State Ice Co. v. Liebmann*, 285 U.S. 262 (1932): "It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *Id.* at 311; *accord*, *Gregory v. Ashcroft*, 501 U.S. at 458 (federalism "allows for more innovation and experimentation in government"). Indeed, State sovereigns often have powerful incentives to find the best public policies in order to attract additional taxpayers, thereby fostering a healthy competition among the

States as the citizenry votes with its feet. *See* McConnell, *Federalism: Evaluating the Founders' Design*, 54 U. Chi. L. Rev. at 1498-1500.

Fourth, a proper federal-State balance helps to enhance liberty by ensuring that each level of government checks the abuses of the other. As Justice Kennedy put it: "Though on the surface the idea may seem counterintuitive, it was the insight of the Framers that freedom was enhanced by the creation of two governments, not one." *United States v. Lopez*, 514 U.S. 549, 576 (1995) (Kennedy, J., concurring); *accord*, *Printz v. United States*, 521 U.S. 898, 920 (1997) (same, quoting Justice Kennedy); The Federalist No. 51, p. 323 (C. Rossiter ed. 1961) (describing this "double security"). A casual override of State prerogatives by the federal judiciary in express preemption cases would severely threaten the federal-State balance vital to this double protection of liberty.

These and other fundamental principles that underlie "Our Federalism" transcend partisan divisions. In the original Executive Order on Federalism, President Ronald Reagan emphasized that "[t]he nature of our constitutional system encourages a healthy diversity in the public policies adopted by the people of the several States according to their own conditions, needs, and desires." Exec. Order No. 12612, 52 Fed. Reg. 41685, § 2(f) (Oct. 26, 1987) (prohibiting agencies from adopting uniform national standards to the maximum extent possible); *see also* President George Bush, *Memorandum on Federalism*, 26 Weekly Comp. Pres. Doc. 264 (Feb. 16, 1990) (reaffirming President Reagan's executive order on federalism).

Similarly, President Clinton's Executive Order on Federalism stressed that "[f]ederalism is rooted in the

belief that issues that are not national in scope or significance are most appropriately addressed by the level of government closest to the people." Exec. Order No. 13132, 64 Fed. Reg. 43255, § 2(a) (Aug. 4, 1999). The order recognized that "States possess unique authorities, qualities, and abilities to meet the needs of the people and should function as laboratories of democracy." *Id.* (section 2(e)). And it sought to promote "a healthy diversity in the public policies adopted by the people of the several States" because "one-size-fits-all approaches to public policy problems can inhibit the creation of effective solutions to those problems." *Id.* (section 2(f)).

In addition to these pragmatic and policy advantages, the requirement that an express preemption provision be unmistakably clear as to its scope also derives from the simple dignity of the States as sovereign entities. As the Court put it in *Alden v. Maine*, 527 U.S. 706 (1999), the States should not be "relegated to the role of mere provinces or political corporations, but retain the dignity, though not the full authority, of sovereignty." *Id.* at 715. The Congress and the federal judiciary would be doing severe violence to sovereign dignity if an ambiguous preemption provision were sufficient to trump the long-standing laws of the sovereign States. *See Medtronic*, 518 U.S. at 488 (declining to find preemption of State common law remedies under the MDA in part because preemption would constitute "serious intrusion into state sovereignty."); Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B. U. L. Rev. 559, 627 (1997) ("[R]equiring that Congress speak clearly will help ensure that its decision to preempt is the

product of a deliberate policy choice. Our system of federalism demands that interference with states' policy decisions to give their citizens tort remedies should be the product of judgment and careful balancing, rather than an unintended result of congressional inattention or imprecision.").

III. THE REQUIREMENT THAT EXPRESS PREEMPTION PROVISIONS BE UNAMBIGUOUS PROMOTES POLITICAL ACCOUNTABILITY.

Requiring express preemption provisions to be clear and unambiguous as to their scope also enhances democratic values by preserving political accountability. It is not uncommon for a majority of citizens to hold a position on an important matter of public policy that is at odds with the position of special interests or factions. *See* The Federalist No. 10, pp. 77-84 (C. Rossiter ed. 1961) (discussing the "mischief of faction"). One could easily imagine a situation in which a vast majority of the voting public prefers that the U.S. Congress refrain from abolishing State damage remedies, but special interests favor abolition and lobby heavily to obtain it. Without a requirement for clarity in express preemption provisions, federal legislators might be tempted to enact an ambiguous provision with the hope that the courts would resolve the ambiguity in favor of preemption, thereby satisfying the special interests while maintaining plausible deniability with their constituents.

Requiring clarity in express preemption provisions prevents federal politicians from side-stepping the political accountability that lies at the heart of our democracy. The Founders emphasized that "the residuary sovereignty of

the States [is] implied and secured by that principle of representation in one branch of the [federal] legislature." The Federalist No. 43, p. 279 (C. Rossiter ed. 1961). In other words, the political checks exercised by voters on elected officials are a primary protector of federalism and the federal-State balance. *See* STARR REPORT ON PREEMPTION, at 50.

Judicial reliance on ambiguities to find preemption would improperly curtail State sovereignty and impose a uniform national policy even in the face of the contrary preferences of the citizenry. If our federal representatives truly want to repeal time-honored common law remedies for corporate malfeasance, let them say so clearly and directly, and then face the political consequences.

Moreover, if ambiguous preemption provisions were sufficient to preempt, unelected federal judges might be tempted to resolve ambiguities by resorting to far less reliable indicators of congressional intent, such as perceived statutory "purposes" or "goals." Most statutes, however, come into existence through the legislative resolution of competing purposes and goals. *E.g., Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 646 (1990) ("[T]here are numerous federal statutes that could be said to embody countless policies."). When the legislative resolution of competing goals is ambiguous with respect to the infringement of State sovereignty, the unelected judiciary is singularly ill-equipped to strike an appropriate balance itself. *Cf. Rapanos v. United States*, 126 S. Ct. 2208, 2234 (2006) (plurality) (cautioning against the practice of "substituting the purpose of the statute for its text"); *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 112 (1992) (Kennedy, J., concurring in part and

concurring in the judgment) ("A freewheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is the Congress rather than the courts that pre-empts state law."); STARR REPORT ON PREEMPTION, at 36 (criticizing the "purpose inquiry" in preemption cases because "a complex of competing legislative policies can be undermined").

For example, in the case at bar, Medtronic might argue that failure to preempt would be inconsistent with a purported "purpose" to promote design innovation. But in enacting the MDA, Congress primarily sought to ensure fully adequate protection of the consumer, "who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. 10688 (1975); *cf.*, *Sprietsma*, 537 U.S. at 64 (2002) (explaining why Congress would preempt State positive law but not State common law to preserve remedies needed to compensate victims). Courts are institutionally ill-positioned to untangle the countless compromises made during the legislative process in an effort to resolve ambiguities in a preemption provision.

In the same way, requiring express preemption provisions to be unambiguous as to their scope avoids the need to resort to legislative history. It is all too easy to scan legislative history as one might look over a "crowd at a party," seeking out only that which is congenial, ignoring that which is unhelpful or unfamiliar. *See Conroy v. Aniskoff*, 507 U.S. 511, 519 (1993) (Scalia, J., concurring in the judgment) (attributing the metaphor to Judge Harold Leventhal). While the risks inherent in legislative history might be unavoidable in other cases involving ambiguous statutes, those risks should not be embraced in order to resuscitate an ambiguous preemption provision that cuts

deeply into State sovereign prerogatives. Requiring textual clarity promotes a more principled approach, one in keeping with the relative institutional capacities of the legislative and judicial branches, and one that affords proper respect to sovereign States.

Nor does the requirement to be unambiguous impose an undue burden on the legislature. The Congress knows full well how to preempt State law tort remedies through a clear textual statement. It easily could have drafted section 360k(a) to include a clear statement preempting all State tort remedies as applied to medical devices. It declined to do so. Instead, section 360k(a) preempts only State and local "requirements," which the *Medtronic* plurality described as "a singularly odd word" to use to refer to common law claims. *Medtronic*, 518 U.S. at 487. Nor did the Congress choose to preempt all such requirements for any given device, but only those requirements that are "different from, or in addition to, any requirement" issued under the MDA to govern the device. This language hardly qualifies as an unambiguous preemption of State common law claims based on general theories of liability that are in no meaningful way a counterpart to any device-specific federal requirement.

IV. THE REQUIREMENT THAT EXPRESS PREEMPTION PROVISIONS BE UNAMBIGUOUS PROMOTES PREDICTABILITY IN THE LAW.

As the court well knows, the general application of clear statement rules in statutory interpretation promotes greater certainty and stability in the law. In the U.S. Appellate Judges Conference Report on Preemption, Judge Starr and his colleagues supported the vigorous application of a clear statement rule in preemption cases for

several reasons, including enhanced clarity and predictability. STARR REPORT ON PREEMPTION, at 50-53. The Report draws helpful analogies to several other clear statement rules the courts use to interpret statutes to enhance clarity and predictability. *Id.*

For example, courts refuse to read a statute as repealing another statute unless the repeal is expressed in clear language. *E.g.*, *National Ass'n of Home Builders v. Defenders of Wildlife*, 127 S. Ct. 2518, 2532 (2007) (reaffirming that "'repeals by implication are not favored' and will not be presumed unless the 'intention of the legislature to repeal [is] clear and manifest.'"; citation omitted). Courts should read a statute as repealing another statute only where the former "expressly contradicts" the latter or where the reading "is absolutely necessary." *Id.* (quoting and discussing authorities). Just as this clear statement rule protects settled expectations derived from reasonable reliance on existing laws, the requirement that preemption provisions be unambiguous insulates reasonable expectations and settled reliance on established State law from undue judicial interference.

Similarly, statutes in derogation of the common law generally "must be strictly construed." *Robert C. Herd & Co. v. Krawill Mach. Corp.*, 359 U.S. 297, 304 (1959); *accord, Shaw* v. *Railroad Co.*, 101 U.S. 557, 565 (1880) (a statute "is not to be construed as making any innovation upon the common law which it does not fairly express."). Nor should statutes be read to expand well-established common law duties "absent some explicit evidence of congressional intent." *Chiarella v. United States*, 445 U.S. 222, 233 (1980). These clear statement rules shield settled expectations and reliance on the common law from judicial

invalidation absent a clear legislative command. In the same way, courts should not construe a preemption provision to overturn State common law remedies absent an unmistakably clear congressional mandate to do so.

The Court also has made clear it will not read statutes to apply retroactively absent clear instructions in the statutory text. *E.g.*, *Landgraf* v. *USI Film Prods.*, 511 U.S. 244, 264-265 (1994) ("'[C]ongressional enactments * * * will not be construed to have retroactive effect unless their language requires this result.' * * * [T]he presumption against retroactive legislation is deeply rooted in our jurisprudence, and embodies a legal doctrine centuries older than our Republic."; quoting *Bowen* v. *Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988)). The reason, of course is that "settled expectations should not be lightly disrupted." *Landgraf*, 511 U.S. at 265. Likewise, settled expectations based on longstanding State laws and protections should not be disrupted without a clear textual statement from Congress requiring this result.

As one scholar put it, "[p]articularly when it legislates in an area affected by state tort law, Congress has much to gain by making explicit its intent to preempt state law. Namely, clarity achieves certainty in statutory application and helps to avoid litigation over legislative meaning." Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B. U. L. Rev. at 627.

CONCLUSION

Because section 360k(a) lacks a clear statement preempting the State common law remedies at issue, the judgment of the court of appeals should be reversed.

Respectfully submitted.

TIMOTHY J. DOWLING
COMMUNITY RIGHTS COUNSEL
1301 Connecticut Ave. NW
Suite 502
Washington, D.C. 20036
(202) 296-6889

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